

REMARKS

After entry of this amendment, claims 45 and 60-76 are pending. Claims 32, 43, 59 and 65 are being cancelled, rendering any rejections thereof moot.

The language in claim 60 is supported, e.g., on page 21, lines 9-10; page 26, lines 10-14, and page 37, lines 20-31.

The language in claim 65 is supported, e.g., on page 21, lines 9-10.

The language in claim 66 and claims 71-73 are supported, e.g., on page 15, lines 13-15.

The language in claim 70 is supported

The language in claims 74-76 is supported on page 15, lines 13-14; page 21, lines 30-31; page 22, line 9, page 24, lines 13 – 24.

No new matter is incorporated by these amendments.

Claim Objections

Claims 62 and 63 have been amended to replace “a” with “the”.

Claim 64 has been amended in order to insert an article prior to each of low density, high density. Claim 65 is amended to avoid the awkward phraseology as requested by the examiner.

This amendment does not affect the scope of the claims, but is believed to address the examiner’s objections.

Rejections under 35 USC §112

A. Second Paragraph

Claim 65 has been amended to recite that it comprises a minigene carrying a heterologous gene. This clarifies what is non-naturally occurring about the recited AAV. Cancellation of claim 59 renders the rejection thereof moot. Claims 68 -69 have been amended to recite the SEQ ID NO: 123, to clarify the sequences.

This amendment is believed to overcome the rejection under 35 USC 112, second paragraph, of claims 65 and 68-69 as being incomplete.

B. First Paragraph

The claims are rejected under 35 USC 112, first paragraph, as not being enabling for any embodiment other than (a) an isolated recombinant AAV comprising an AAV9 capsid wherein the AAV9 capsid is SEQ ID NO:123 or (b) comprises amino acids 203-736 of SEQ ID NO:123, or (c) an isolated chimeric capsid vp1, vp2 or vp3 protein wherein the chimeric capsid protein comprises sequences from SEQ ID NO: 123 selected from the group consisting of aa25-28, aa137-143, aa154-156, aa171-173, aa182-186, aa185-198, aa260-273, aa262-264, aa262-274, aa381-383, and aa670-706.

Applicant respectfully traverses this rejection.

The specification provides support for other AAVs having capsids which are at least 95% identity to the AAV9 vp1 protein and at least 95% identity to the AAV9 vp3 protein.

The application provides two other novel AAV sequences, hu31 [SEQ ID NO:121] and hu32 [SEQ ID NO:122] which are 95% identical to AAV9. The hu32 AAV has a 100% identical vp3 amino acid sequence; over the full-length of the vp1 proteins, hu32 and AAV9 differ in amino acid sequence by 1.9%. Additionally, the hu31 sequence is 2.2% identical to AAV9 over the full-length vp1 protein. Thus, the specification does provide support for other AAVs which are within 5% of the vp3 of AAV9 (*i.e.*, at least 95% identity to amino acids 203-736 of SEQ ID NO:123) and within 5% of the vp1 of AAV9 (*i.e.*, at least 95% identity to amino acids 1 to 736

of SEQ ID NO: 123). Thus, the specification provides examples of other AAVs which can be used to construct AAV-based vectors.

The examiner argues that the claim is drawn to a capsid comprising a single protein whereas the art requires vp1, vp2 and vp3 to form a capsid.

Applicants believe that the presence of vp1, vp2 and vp3 capsid proteins was implicit in the claim, which recited the presence of an AAV having a capsid. However, the claims have been amended to explicitly recite these elements. Thus, the required structure of the AAV capsids is provided.

The examiner argues that the recitation of the capsid protein only requires "one or more AAV capsid protein fragments from one or more different AAVs", and alleges that they encompass a number of non-productive fragments.

Applicants believe that the recitation in the claims that the capsid contains vp1, vp2 and vp3 proteins clarifies that the structure required for an intact capsid is provided by the claim. As described in the specification, methods for producing an AAV vector containing an AAV capsid were well known as of the effective date of this application. Thus, one of skill could readily have prepared AAV containing artificial (chimeric) capsids based on the information provided in this specification, without undue experimentation.

In view of these remarks and this amendment, Applicant requests reconsideration and withdrawal of this rejection.

Applicant requests that this application be permitted to pass to issue.

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The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to our Deposit Account, Number 08-3040.

Respectfully submitted,

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